NASA Procedural Requirements

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COMPLIANCE IS MANDATORY FOR NASA EMPLOYEES

NASA Health and Medical Requirements for Human Space Exploration

Responsible Office: Office of the Chief Health & Medical Officer

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Preface

P.1 Purpose

a. This document provides the procedural requirements and processes for the NASA Health and Medical System for Human Space Exploration.

b. NASA fulfills all requirements of this NASA Procedural Requirements (NPR) to protect the health and safety of crewmembers involved in space flight activities and enable successful human space exploration.

P.2 Applicability

a. This NPR is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers. This NPR applies to the Jet Propulsion Laboratory, a Federally Funded Research and Development Center, other contractors, and parties to agreements only to the extent specified or referenced in the appropriate contracts, grants, or agreements.

b. The requirements in this NPR apply to all human space exploration activities including, but not limited to, space systems, space suits, habitats, planetary rovers, and surface vehicles.

c. The requirements in this NPR applies to internationally provided space systems as documented in distinct separate agreements, such as joint or multilateral agreements.

d. The requirements in this NPR supercede requirements imposed by other Federal Government agencies.

e. In this directive, all document citations are assumed to be the latest version unless otherwise noted.

f. In this NPR, a requirement is identified by "shall," a good practice by "should," permission by "may" or "can," expected outcome or action by "will," and descriptive material by "is" or "are" (or another form of the verb "to be").

P.3 Authority

a. National Aeronautics and Space Act, as amended, 51 U.S.C. 20113(a).

b. NPD 1000.0, NASA Governance and Strategic Management Handbook.

c. NPD 1000.3, The NASA Organization.

d. NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration.

P.4 Applicable Documents and Forms

a. NPD 7100.8, Protection of Human Research Subjects.

b. NPD 7120.4, NASA Engineering and Program/Project Management Policy.

c. NPD 8900.1, NASA Medical Operations Responsibilities in Support of Human Space Flight Programs.

d. NPD 8900.3, Astronaut Medical and Dental Observation Study and Care Program.

e. NPR 1382.1, NASA Privacy Procedural Requirements.

f. NPR 1441.1, NASA Records Management Program Requirements.

g. NPR 7120.5, NASA Space Flight Program and Project Management Requirements.

h. NPR 7120.8, NASA Research and Technology Program and Project Management Requirements.

i. NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.

j. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health.

k. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 2 - Human Factors, Habitability and Environmental Health.

l. OCHMO 80771201MED, NASA Crewmembers Medical Standards, Volume 1 - Selection and Periodic Certification.

m. JSC-66306, Data Sharing Policy for Release of NASA Protected Health and Research Information.

n. NPD 8020.7, Biological Contamination Control for Outbound and Inbound Planetary Spacecraft.

P.5 Measurement and Verification

Measurements of compliance for this NPR is determined by whether operational managers adhere to the requirements and follow the processes specified in this NPR. The Chief Health and Medical Officer (CHMO) through Agency authority and its Health and Medical Technical Authority (HMTA) function will monitor compliance. This will include appropriate reviews by, and reporting to, the CHMO.

P.6 Cancellation

NPR 8900.1A, NASA Health and Medical Requirements for Human Space Exploration, dated July 17, 2012.

Chapter 1. Institutional and Programmatic Health and Medical Requirements and Responsibilities for Human Space Exploration

1.1 Overview

1.1.1 As stated in NASA Policy Directive (NPD) 8900.5, it is NASA's policy to provide a safe and healthy environment for crewmembers, including provision of health, medical care, environmental systems, programs, and countermeasures for all mission phases; establishment of health and medical, human performance, habitability, and environmental standards; and, sponsorship of health-related and clinical research.

1.1.2 This NPR establishes health and medical requirements for human space flight and the responsibilities for their implementation.

a. The policies for NASA medical operations and astronaut care are provided in NPD 8900.1 and NPD 8900.3.

b. The policy for protection of human research subjects is provided in NPD 7100.8.

c. The requirements for implementation of the Health and Medical Technical Authority are provided in NPR 7120.11.

1.2 NASA Health and Medical Standards for Human Space Exploration

1.2.1 NASA health, human performance, and medical standards for human space exploration will be established according to the process presented in Appendix C. The health, human performance, and medical standards apply to all NASA human space flight programs and NASA-contracted human space flight programs, as specified in contractual specifications. Health, human performance, and medical standards for human space exploration are documented as follows:

a. NASA-STD-3001 Vol. 1 standards cover the main physiologic parameters associated with the health and successful operation of the human system. They are not all encompassing but do address those areas where the human system has shown particular vulnerability in response to adaptation or exposure to applicable mission environments. These include appropriate levels of medical care, permissible exposure limits, fitness-for-duty criteria, and permissible outcome limits as a means of defining successful operating criteria for the human system.

b. NASA-STD-3001 Vol. 2 addresses habitability and environmental health, focuses on human physical and cognitive capabilities and limitations and defines standards for spacecraft (including, vehicles, habitats, and suits), internal environments, facilities, payloads, and related equipment, hardware, and software systems with which the crew interfaces during space operations.

c. OCHMO 80771201MED establishes and documents standards that address health and medical screening, evaluation, and certification of crewmembers.

1.2.2 Management and privacy of medical information and data are as follows:

a. Collection, control of records, communications, and public release of all astronaut medical care, biomedical, and medical research data will comply with the privacy requirements of NPR 1382.1 and the provisions of the Privacy Act of 1974, as amended.

b. Records will be disposed of in accordance with NPR 1441.1.

c. Requests, reviews, and potential release of human medical and research data will also comply with the established NASA policy, JSC-66306.

1.3 Institutional and Programmatic Roles and Responsibilities

1.3.1 General

a. The roles and responsibilities of senior management are defined in part in NPD 1000.0 and NPD 1000.3.

b. NPD 8900.5 defines explicit health and medical responsibilities for human space exploration. NPD 7120.4, NPR 7120.5, NPR 7120.8, and other NASA directives define the explicit program/project management responsibilities of program and project managers.

c. The NASA OCHMO shall serve as the office of primary responsibility providing leadership, policy direction, assessment, and coordination of the technical requirements and process compliance verification for this NPR.

1.3.2 The Chief Health and Medical Officer (CHMO) or designee, shall:

a. Promulgate health and medical policy for human space flight.

b. Serve as the NASA Health and Medical Technical Authority (HMTA).

c. Ensure Agency-wide implementation of HMTA (including, HMTA awareness), as described in NPR 7120.11.

d. Establish and maintain human health, human performance, and medical standards for space flight.

e. Establish and maintain mission-specific human health, human performance, and medical standards for commercial space flight in collaboration with the Federal Aviation Administration for NASA astronauts.

f. Review and approve all human health, human performance, and medical requirements for space exploration.

g. Review and deliberate on requests for waivers/deviations to human health, human performance, and medical requirements originated by human space flight programs and projects.

h. Participate in Design Reference Mission (DRM) discussions and Program/Project Pre-Formulation activities to assess the need for operational exceptions to health, human performance and medical standards, as described in Appendices E, F, and G.

i. Provide risk assessments for requested operational non-compliance (waiver, deviation, exception) with a health, human performance, or medical standard, as described in Appendices E, F, and G.

j. Review and approve all human health, human performance, medical research and technology recommendations, and deliverables that enable human space exploration.

k. Approve operational implementation of research and technology deliverables that enable human space exploration.

l. Approve operational use of health and medical systems and technologies prior to their use in space exploration.

m. Consult with the Science Mission Directorate (SMD) AA or designee to ensure that medical planetary protection requirements for space exploration are coordinated with existing health and medical policy for human space exploration.

1.3.3 The Associate Administrator (AA) of the Human Exploration and Operations Mission Directorate (HEOMD) or designee, shall:

a. Support the formulation of human health, human performance, and medical requirements that meet Agency-level human system standards.

b. Designate a senior manager for crew health and safety to advise the Mission Directorate Associate Administrator (AA) on crew human health, human performance, and medical issues.

c. Recommend requirements for health, human performance, medical care, and environmental systems, programs, and countermeasures for all mission phases and establish milestones for deliverables.

d. Provide on-orbit resources necessary to meet these milestones.

e. Recommend policies applicable to crew human health, human performance, and medical matters.
f. Implement human health, human performance, and medical requirements.

g. Ensure that the OCHMO is included in Design Reference Mission (DRM) discussions and Program/Project Pre-Formulation activities to assess the need for operational exceptions to health, human performance, and medical standards as described in Appendices E, F, and G.

h. When necessary, initiate a request for an operational exception to a health, human performance, and medical standard in accordance with the processes described in Appendices E, F, and G.

i. Review space medicine operations and results on a periodic basis.

j. Define, plan, conduct, and oversee NASA-sponsored human health, human performance, and medical research and technology development.

k. Develop human health, human performance, and medical research and technology deliverables to an appropriate stage of readiness level for final review, approval and implementation and recommend timelines for implementation.

l. Oversee the implementation of human health, human performance, and medical research and technology deliverables once approved.

1.3.4 The AA for the Science Mission Directorate (SMD) or designee shall coordinate with the CHMO regarding health and medical issues related to planetary protection for human space exploration.

1.3.5 The Johnson Space Center (JSC), Center Director or designee, shall:

a. Concur with the CHMO appointment of a JSC Chief Medical Officer (CMO).

b. Develop a JSC HMTA Implementation/Awareness Plan, as described in NPR 7120.11.

c. Medically screen, evaluate, and certify crewmembers.

d. Conduct clinical evaluations and monitor astronaut health at regular intervals to determine medical status during ground-based training, space flight, and post-flight.

e. Provide medical care to maintain the crewmember's ability to perform assigned duties before, during, and after space flight.

f. Provide health maintenance and preventive care to maintain the crewmember's ability to perform assigned duties before, during, and after space flight.

g. Provide post-flight health reconditioning to assist the astronaut to return to functional baselines in the areas of physical fitness and physiological and behavioral health.

h. Provide mission-specific medical, performance, and behavioral health training for crewmembers.

i. Provide programs aimed at maintaining the health status and performance of crewmembers to enable their ability to function and perform all assigned duties over the duration of their career as an astronaut.

j. Establish, implement, and update a program of preventative medicine based on research findings, human health, human performance, medical lessons-learned, current standards of medical practice, risk management data (health and performance effects), and expert recommendations.

k. Develop and manage the Lifetime Surveillance of Astronaut Health (LSAH).

l. Establish, document, and implement a NASA policy which allows for request, review of, and potential release of human medical and research data.

1.3.6 The JSC CMO shall:

a. Exercise HMTA for activities conducted at JSC and delegated human space flight HMTA activities at other NASA Centers, as described in NPR 7120.11.

b. Assign a point of contact for human space flight HMTA issues at other NASA Centers as, described in NPR 7120.11.

c. Provide recommendations for health, medical, environmental, habitability, and human factors standards and requirements.

1.3.7 In accordance with NPR 7120.11, the CMOs at Centers other than JSC shall:

a. Establish interfaces with assigned points of contact from the JSC for human space flight HMTA issues.

b. Assist with the identification and resolution of HMTA human space flight issues.

c. Provide recommendations for health, medical, environmental, habitability and human factors standards and requirements.

1.3.8 Clinical decision will be made in accordance with the NASA Medical Policy Board (MPB) and Aerospace Medicine Board (AMB) responsibilities.

Chapter 2. Human Health, Human Performance and Medical System Design Requirements

2.1 System Design Requirements

2.1.1 Program/Project Managers shall formulate human health, human performance, and medical system design requirements in compliance with NASA Space Flight Human System Standard, volumes 1 and 2.

2.1.2 The space system (inclusive of the vehicle, ground systems, and supporting infrastructure) provides the following systems and capabilities:

a. Diagnostic and treatment systems in compliance with established level of medical care standards.

b. Capability for medical services to support all phases of a mission in compliance with established level of medical care standards.

c. Health maintenance, preventive, performance, and countermeasure systems in compliance with established space flight crew health standards.

d. Protected medical communications, consistent with privacy requirements, the Privacy Act of 1974, and established crew health standards.

e. A healthy and safe environment in compliance with established habitability and environmental health standards.

f. System implementations that meet both established human performance and constraints.

2.1.3 The NASA HMTA shall approve all health, human performance, and medical system design requirements.

Chapter 3. Human Health, Human Performance and Medical Research and Technology

3.1 Requirements

3.1.1 HEOMD shall develop and recommend human health, human performance, and medical research and technology development requirements.

3.1.2 Space Technology Mission Directorate (STMD) shall develop research and technology deliverables for human health and performance, with cross-reference to the portfolio managed by the AA of HEOMD, to an appropriate stage of readiness level for final review, approval, and implementation. The Office of the Chief Technologist will integrate technology development priorities for human health and performance into the NASA Strategic Technology Investment Plan.

3.1.3 The CHMO shall:

a. Review and approve, with modifications as needed, all proposed human health, human performance, and medical research and technology development requirements.

b. Review and assess the progress of human health, human performance, and medical research and technology development programs against established health and medical standards.

3.2 Operational Implementation

The CHMO shall approve, approve with revision, defer, or reject, as necessary, all human health, human performance, and medical research deliverables and contractor human health, human performance, medical technology, and systems deliverables prior to implementation by the appropriate operational community using the Transition to Operations Review Process (TORP) described in Appendix D.

Appendix A. Definitions

Aerospace Medicine Board (AMB): The AMB at JSC is a clinical and implementation body for addressing crew medical qualifications and crew medical status made up of NASA flight physicians.

Health: The physiological, psychological, performance and dental status, and well-being of an individual.

Health and Medical Technical Authority (HMTA): HMTA provides independent oversight of all health, medical, and crew performance matters that either arise in association with the execution of NASA programs or projects or are embedded in NASA programs or projects. HMTA implements the responsibilities of OCHMO to assure that Agency health and medical policy, requirements, and technical standards are addressed in program/project management, when applicable and appropriate. The Technical Authority process is a part of NASA's system of checks and balances to provide independent oversight of programs and projects in support of safety and mission success through the selection of specific individuals with delegated levels of authority. Individuals with these formal delegations are Technical Authorities.

Medical: The care and treatment of an individual for illness or injury.

Medical Policy Board (MPB): The MPB at HQ is responsible for health and medical policy and oversight of medical activities and is comprised of full-time Federal employee physicians cognizant of aerospace medicine.

Operational Exception: An exception granted by the NASA Administrator (or designee) to a human health, human performance, and/or medical standard. Based on the ethical, policy criteria, and factors, uses the processes described in this NPR when a standard cannot be fully met or if the level of knowledge for a given condition is sufficiently limited that an adequate standard cannot be developed.

Planetary Protection: Policies, requirements, and procedures designed to prevent biological contamination of other solar system bodies that might jeopardize scientific investigations on the origins and evolution of life, as well as to prevent the potential for harmful contamination of the Earth by extraterrestrial materials carried on board returning spacecraft.

Transition to Operations Review Process (TORP): An assessment of the effectiveness and operational readiness of human health-related research and technology products and deliverables. It provides a clear channel for human health and medical-related flight and ground research results and technology development that can impact crew health and performance for transition to tools available to support Agency human space flight programs.

Appendix B. Acronyms

AA	Associate Administrator
AMB	Aerospace Medicine Board
CMO	Chief Medical Officer
CHMO	Chief Health and Medical Officer
DRM	Design Reference Mission
FOD	Flight Operations Directorate
HH&P	Human Health & Performance Directorate
HMTA	Health and Medical Technical Authority
HSRB	Human System Risk Board
HEOMD	Human Exploration and Operations Mission Directorate
HSRB	Human System Risk Board
IOM	Institute of Medicine
JPL	Jet Propulsion Laboratory (a Federally Funded Research and Development Center)
JSC	Johnson Space Center
KDP	Key Decision Point
LOC/LOM	Loss of Crew/Loss of Mission
LSAH	Lifetime Surveillance of Astronaut Health
MPB	Medical Policy Board
NPD	NASA Policy Directive
NPR	NASA Procedural Requirements
OCHMO	Office of the Chief Health and Medical Officer
SMD	Science Mission Directorate
TORP	Transition to Operations Review Process
U.S.C.	United States Code

Appendix C. Process for Establishing Human Health, Human Performance and Medical Standards

C.1 Standard Setting Process

C.1.1 Health, human performance, and medical standards are initiated by the CHMO and are developed under the supervision of the delegated HMTA (i.e., JSC CMO) with participation of other Centers and external experts. Final approval is executed by the CHMO.

C.1.2 Health, human performance, and medical standards are established by the OCHMO per the following process:

a. A recommendation for development of a new standard or revision of an existing standard may originate anywhere in the Agency, such as in the OCHMO, the HEOMD, the AMB, or the Human Health and Performance Directorate (HH&P) at JSC and is forwarded to the CHMO for consideration.

b. The CHMO reviews the recommendations and, if warranted, initiates development or revision of a standard and establishes a standards development team under the supervision of the delegated HMTA.

> *Note: The standards development team includes internal NASA experts and may include external discipline experts.*

c. The standards development team drafts the standard, which is reviewed according to the process established by the delegated HMTA with the concurrence of the CHMO.

d. The delegated HMTA then reviews the draft standard and provides a recommendation for approval of the new or revised standard to the CHMO.

e. The CHMO determines whether or not independent technical review of the draft standard is required by an external team and convenes a team to conduct the review, where appropriate.

f. The draft/revised standards are distributed to affected and interested parties (e.g., Flight Operations Directorate/Astronaut Office, mission directorates, functional staff offices, Centers, etc.) for review and comment.

g. The draft/revised standards are presented to the NASA MPB, which provides a recommendation for approval to the CHMO.

h. The CHMO considers comments and recommendations and either rejects, recommends further modifications, or executes final approval of the standard.

i. Implementation of the standards is overseen by the delegated HMTA.

j. Periodic review of the standards occurs as required.

Appendix D. Transition to Operations Review Process (TORP)

D.1 The Transition to Operations Review Process (TORP) is designed to assess the effectiveness and operational readiness of human health, human performance, and medical research and technology products and deliverables. It provides a clear channel for human health, human performance, and medical flight and ground research results, and technology development that can impact crew health and performance for transition to tools available to support Agency human space flight programs.

D.2 The TORP review process will be conducted according to the process described below. It will be applied to newly proposed human health, human performance, medical procedures, practices, processes (including, when deemed appropriate, "off-label" uses of medications, therapies, and technologies), countermeasures, or technologies resulting from NASA-sponsored research or technology development that are designed to maintain the health, performance, and/or support the medical care of space flight crews. The initial evaluation will be through JSC human space flight HMTA management structure before a recommendation is made to the CHMO for the final review.

a. The submitting organization presents a proposal for TORP review of a research or technology deliverable or product to the appropriate JSC configuration control board and/or the Aerospace Medicine Board (AMB) for subsequent consideration by the JSC Human System Risk Board (HSRB). The proposal will include the following documentation:

(1) A detailed description of the deliverable or product, its intended use or application, and a description of how the deliverable or product addresses a NASA-identified critical risk, medical, health, performance issues, or application.

(2) Data demonstrating the efficacy, effectiveness, or utility of the deliverable or product.

(3) Data demonstrating the operational validation of the deliverable or product.

(4) An implementation plan of how the product or deliverable is to be used or applied (e.g., protocol, dosing regimen, scope of use).

(5) An analysis of the mission resources (e.g., crew time, volume, power, etc.) necessary to implement the product or deliverable.

(6) A summary of the developmental process and milestones the product or deliverable underwent.

b. Upon recommendation by the HSRB, the submitting organization provides a written request for TORP review of a research or technology deliverable or product to the JSC CMO. The JSC CMO recommends to the CHMO that a panel be convened.

c. The submitting organization provides the documentation package described above and board recommendations to the CHMO in advance of the TORP review.

d. Depending on the nature of the product or deliverable, at least one of the reviews below will be conducted to evaluate the operational readiness of the product or deliverable. The CHMO determines which type of review(s) should be conducted.

(1) Operational assessment - The developmental history and overall utility and effectiveness of the

product or deliverable will be assessed by a panel of NASA internal experts with relevant technical and operational expertise for the product or deliverable.

(2) Scientific/technical review - The underlying scientific and/or technical basis and rationale, as well as operational utility and effectiveness of the product or deliverable will be assessed by a panel of NASA internal and external experts with relevant scientific, technical, and operational expertise for the product or deliverable.

(3) Medical Policy Board review - The product or deliverable supporting documentation, and any results and recommendations from the other two reviews, will be reviewed by the Medical Policy Board for concurrence on recommended course of action.

e. The TORP panel(s) provides one of the following recommendations for consideration by the CHMO:

(1) Approve: The CHMO will certify the product or deliverable for the NASA human spaceflight operations;

(2) Approve with Revision/Recommendation: The CHMO will certify the product or deliverable for NASA human spaceflight operations with revisions or recommendations to the implementation plan or scope of use, as indicated by the TORP review panel;

(3) Defer: A decision regarding the product or deliverable will be deferred until additional information can be supplied to the review panel. This may be a request for additional supporting documentation or for additional data collection and/or experimentation; or

(4) Reject: The product or deliverable will not be certified for NASA human spaceflight operations.

f. The OCHMO will convey, in writing, the results of the TORP review to the submitting organization and to the JSC CMO.

g. Once approved, the product or deliverable will be available for use according to established NASA policy.

Appendix E. Process for Evaluating an Operational Exception to Health, Human Performance, and Medical Standards

E.1 Operational Exception to a Health, Human Performance, and Medical Standard

E.1.1 An operational exception defined in this appendix shall only be considered when it is known that a health, human performance, or medical standard cannot be met and the risk to the crew reaches a level which requires a more thorough review, including the consideration of ethical and policy factors. This determination shall be made by the Health and Medical Technical Authority.

E.1.2 Exception to a health, human performance and medical standard shall be considered an operational exception under the authority of the NASA Administrator (Appendix G).

E.1.3 The evaluation of the operational exception to a health, human performance, and medical standard is based on a three-level decision framework that examines:

a. Level 1: Decisions about allowing risk to astronaut health and safety in excess of that permitted by health/medical standards (Appendix G);

b. Level 2: Decisions about undertaking specific missions (see E.2); and

c. Level 3: Decisions concerning individual astronaut participation and crew composition (see E.3).

E.2 Operational Exception to a Health, Human Performance and Medical Standard for a Mission

E.2.1 Determining the need for an operational exception to a health, human performance, and medical standard which cannot be met for all crew members during a proposed human space flight mission should originate early in the Program/Project development.

E.2.2 The AA of the Human Exploration and Operations Mission Directorate (HEOMD) will:

a. Include the CHMO in Design Reference Mission (DRM) discussions and Program/Project Pre-Formulation activities to assess the need for an operational exception to a health, human performance, and medical standard.

b. In consultation with the CHMO, determine the Program/Project Key Decision Point (KDP) by which evaluation of the operational exception (including, approval by the NASA Administrator) must be finalized before the AA requests the operational exception.

c. Document the identification and evaluation of the operational exception in appropriate Risk Management processes.

E.2.3 When it is known that a health, human performance, and medical standard cannot be met for

all crew members during a proposed human space flight mission, evaluation of an operational exception to that standard for the mission can be considered per the following process:

a. The Health and Medical Technical Authority (i.e., CHMO and JSC HMTA) will conduct a health/medical risk assessment for the proposed mission and will provide the impact to the mission LOC/LOM by not meeting the health, human performance and medical standard, along with the impact to crew member's long-term health (post-mission health).

b. The CHMO risk assessment will be reviewed through the established risk management process of the Human System Risk Board and the HMTA and provided to HEOMD.

c. The CHMO will provide recommendations to mitigate the human health and performance impacts of the operational exception.

d. HEOMD will combine the CHMO assessment with the operational, engineering, and safety analyses conducted by the Mission Directorate and the Office of the Chief Engineer (OCE) and the Office of Safety and Mission Assurance (OSMA) technical authorities to develop the overall mission risk assessment.

e. Prior to the Program/Project KDP identified in D.2.3, presentation of the mission's risk posture, including the operational exception, will be made to NASA senior management through the established reporting mechanisms (i.e., Agency Program Management Council).

f. The NASA Administrator, in consultation with senior management, will make the final determination to accept the operational exception to the health, human performance, and medical standard for the mission (Appendix G). In making this decision, factors that will be considered include:

(1) the overall risk assessment for the mission;

(2) a balancing of the overall risk with the ethical principles and responsibilities identified in Appendix F; and

(3) other characteristics of the mission (e.g., national priorities, time urgency, expected benefit, mission design to meet objectives compared to other alternatives).

g. If the operational exception to a health, human performance, and medical standard is approved, the relevant ethical responsibilities and principles identified in Appendix F must be met (e.g., informed decision, provision of appropriate medical monitoring, and health care), the actions to meet them will be identified, and implemented by the appropriate Agency organizations.

E.3 Operational Exception to a Health, Human Performance and Medical Standard for an Individual

E.3.1 When, because of operational or programmatic necessity, the operational community wants to offer a flight assignment to an individual crewmember under circumstances where a crew health, human performance, and medical standard cannot be met for the crewmember, an operational exception to that standard for the individual can be evaluated per the following process:

a. The Crew Selection Authority will develop a rationale and justification for the request to except the health, human performance and medical standard, which may include:

(1) operational factors;

(2) programmatic factors; and

(3) consideration and possible balancing of competing ethical principles and responsibilities as identified in Appendix F (e.g., avoid harm vs. fairness and equality of opportunity).

b. The Aerospace Medicine Board will assess the risk of the health, human performance, and medical standard being exceeded for the individual and provide the assessment to the HMTA, who will then provide a risk analysis on exceeding the standard to the Crew Selection Authority and the individual.

c. Based on the original proposal and the HMTA assessment, the Crew Selection Authority, in consultation with Agency senior management and other relevant stakeholders (e.g., astronaut office) will make a determination regarding crew assignments. The final decision as to whether an operational exception to a health/medical standard will be granted for an individual crew member will be made by the NASA Administrator. (Appendix G).

d. An individual assigned to a mission in this situation will fly under an operational exception under the authority of the NASA Administrator.

e. Flight assignments under these conditions should only be made with full assurance by the Agency that the appropriate ethical responsibilities identified in Appendix F will be met; including, the understanding and acceptance by the crewmember of the risks involved, assurance that all feasible means of exposure control will be implemented, and assurance that all feasible attempts to monitor long-term health effects will be made.

Appendix F. Ethical Principles and Responsibilities

F.1 Principles

F.1.1 When appropriate, the following ethical principles should be considered when developing, revising, and implementing health, human performance and medical standards and when evaluating an exception to a health, human performance and medical standard as described in Appendix D:

a. *Avoid harm*—the principle includes the duty to prevent harm, exercise caution, and remove or mitigate harms that occur. All feasible measures should be taken to minimize the risks to astronauts from long-duration and exploration space flights, including addressing uncertainties through approaches to risk prevention and mitigation that incorporate safety margins and include mechanisms for continuous learning that allow for incremental approaches to risk acceptance.

b. *Beneficence*—the principle to provide benefit to others. The potential benefits of a specific mission including its scientific and technological importance, as well as its potential beneficiaries including, current and future astronauts and members of society at large should be considered in decision-making process regarding crew health standards.

c. *Favorable balance of risk and benefit*—the principle to seek both a favorable and acceptable balance between the risk of harm and potential for benefit. The risks and benefits of space exploration activities and the uncertainties attached to each should be systematically assessed, drawing on the totality of available scientific evidence, and ensuring that benefits sufficiently outweigh risks.

d. *Respect for autonomy*—the principle to ensure that individuals have both the right to self-determination and processes in place to exercise that right. Astronauts should be able to exercise that right. Astronauts should be able to exercise voluntariness to the extent possible in making personal decisions regarding participation in proposed missions, that they have all available information regarding the risks and benefits of the proposed mission, and that they continue to be apprised of any updates to risk and benefit information throughout the mission.

e. *Fairness*—the principle requires that equals be treated equally, that burdens and benefits be distributed fairly, and that fair processes be created and followed. Decision-making surrounding missions should explicitly address fairness, including the distribution of the risks and benefits of the mission, crew selection, and protections for astronauts after missions.

f. *Fidelity*—the principle recognizes that individual sacrifices made for the benefit of society may give rise to societal duties in return. Appropriate health care and medical oversight should be provided to astronauts participating in space missions.

F.2 Responsibilities

F.2.1 When appropriate, the following ethical responsibilities should be considered when developing, revising, and implementing health, human performance and medical standards, and when evaluating an exception to a health, human performance and medical standard as described in

Appendix D:

a. Fully inform astronauts about the risks of long-duration and exploration space flights and make certain that the informed decision-making process is adequate and appropriate.

b. Adhere to a continuous learning strategy (including, health surveillance and data collection) to ensure that health, human performance and medical standards evolve and improve over time and are informed by data gained before, during, and after long-duration and exploration space flights, as well as from other relevant sources.

c. Solicit independent advice about any decision to allow any specific mission that fails to meet NASA health, human performance and medical standards or any decision to modify these standards.

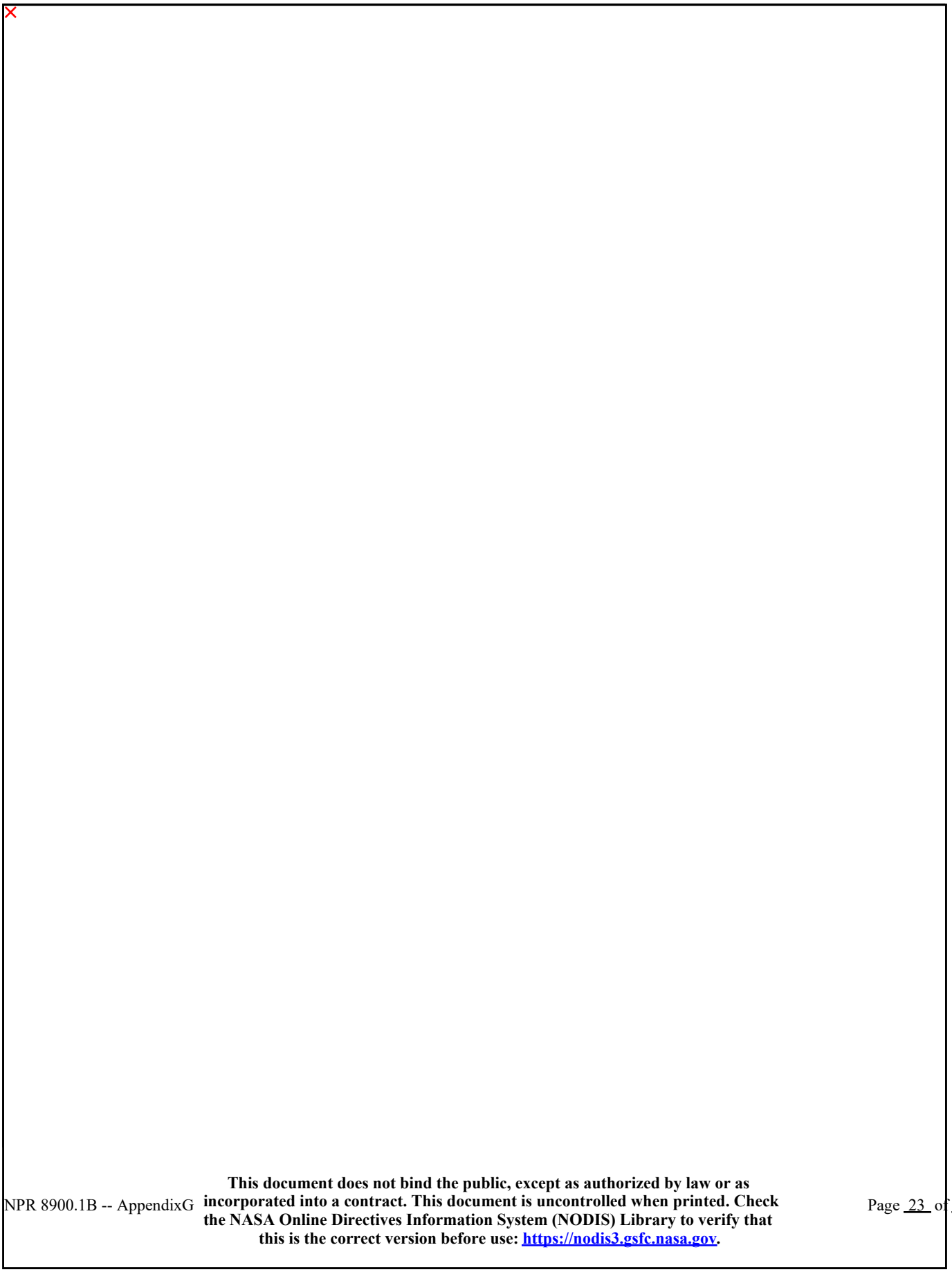
d. Communicate with all relevant stakeholders the rationale for, and possible impacts related to any decision about health, human performance and medical standards in a procedurally transparent, fair and timely manner, providing adequate opportunity for public engagement.

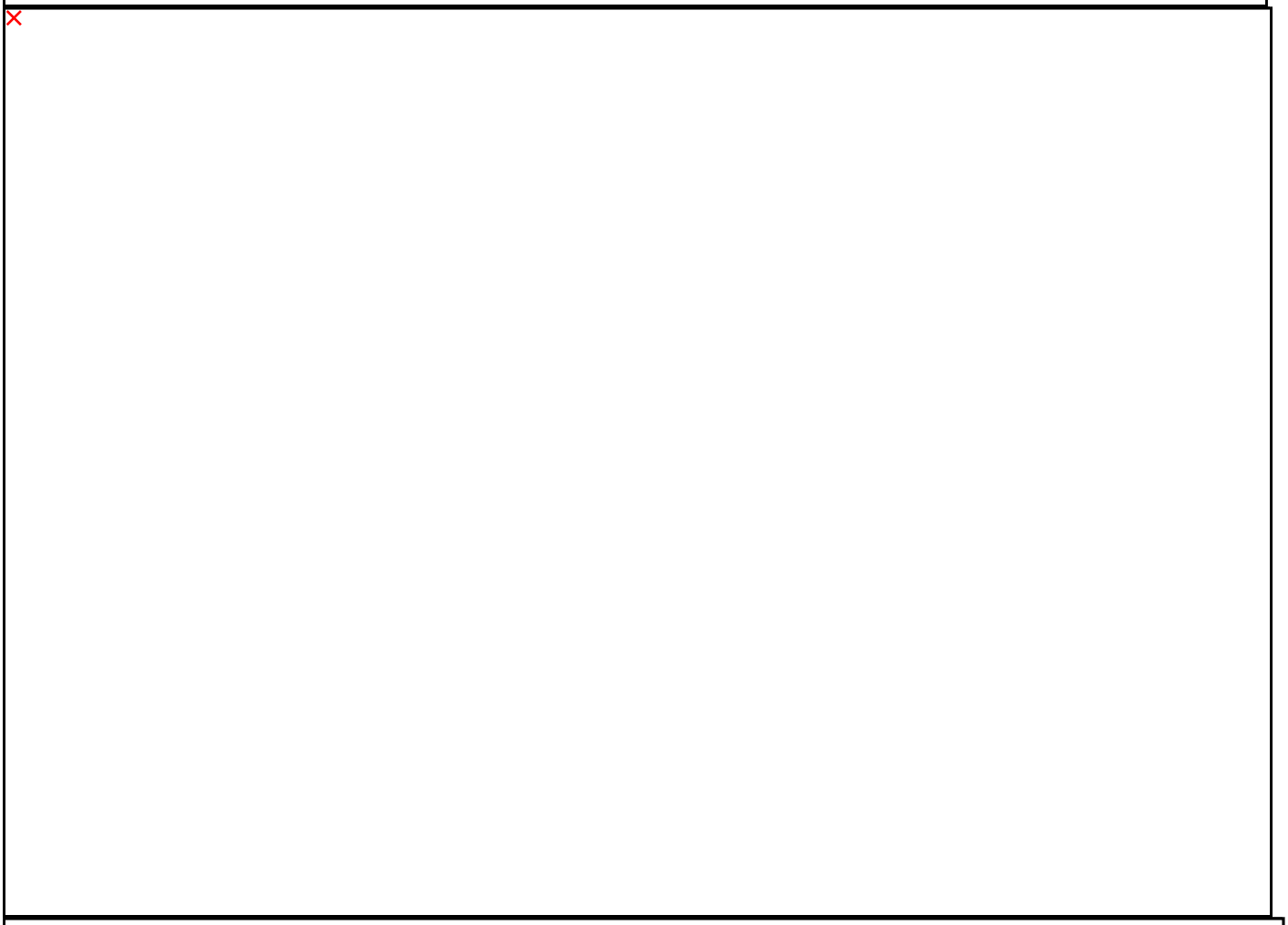
e. Provide equality of opportunity for participation in long duration and exploration space flights to the fullest extent possible without jeopardizing mission operations.

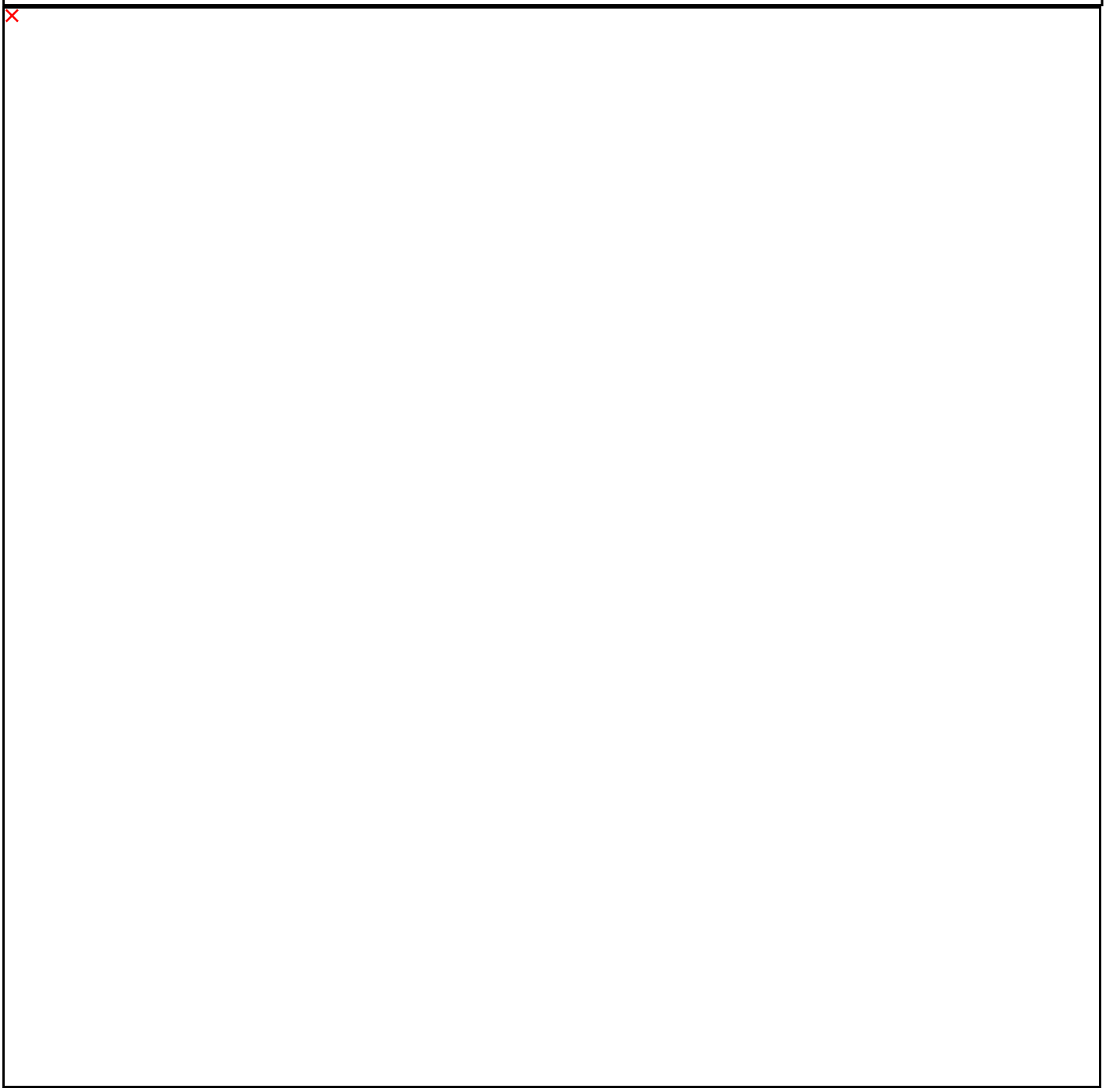
f. Provide comprehensive health care and medical oversight for astronauts to protect their health, support ongoing evaluation of health, human performance and medical standards, improve mission safety, and reduce risks for current and future astronauts.

g. Develop and apply policies that appropriately and sufficiently protect the privacy and confidentiality of astronaut health data.

Appendix G. Copy of the Administrator's Letter of Direction to OCHMO and APMC Decision Memorandum







Appendix H. Reference Documents

H.1 5 U.S.C. 522a, The Privacy Act of 1974, as amended.

H.2 NPD 7100.8, Protection of Human Research Subjects.

H.3 NPD 7120.4, NASA Engineering and Program/Project Management Policy.

H.4 NPD 8900.1, NASA Medical Operations Responsibilities in Support of Human Space Flight Programs.

H.5 NPD 8900.3, Astronaut Medical and Dental Observation Study and Care Program.

H.6 NPR 1382.1, NASA Privacy Procedural Requirements.

H.7 NPR 1441.1, NASA Records Management Program Requirements.

H.8 NPR 7120.5, NASA Space Flight Program and Project Management Requirements.

H.9 NPR 7120.8, NASA Research & Technology Program and Project Management Requirements.

H.10 NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.

H.11 NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health.

H.12 NASA-STD-3001, NASA Space Flight Human System Standard, Volume 2 - Human Factors, Habitability and Environmental Health.

H.13 OCHMO 80771201MED, NASA Crewmembers Medical Standards, Volume 1 - Selection and Periodic Certification.

H.14 JSC-66306, Data Sharing Policy for Release of NASA Protected Health and Research Information.